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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.               | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------------------|------------------|
| 10/072,320   | 02/07/2002  | Russell Mumper       | 434-400 DIV                       | 5127             |
| 1009   | 7590        | 08/16/2010           |                                   |                  |
| KING & SCHICKLI, PLLC<br>247 NORTH BROADWAY<br>LEXINGTON, KY 40507 |             |                      | EXAMINER<br>ROGERS, JAMES WILLIAM |                  |
|  |             |                      | ART UNIT                          | PAPER NUMBER     |
|  |             |                      | 1618                              |                  |
|  |             |                      | MAIL DATE                         | DELIVERY MODE    |
|  |             |                      | 08/16/2010                        | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/072,320

**Applicant(s)**

MUMPER ET AL.

**Examiner**

JAMES W. ROGERS

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33, 34, 36-57 and 63-68 is/are pending in the application.
- 4a) Of the above claim(s) 47-50 and 52-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33, 34, 36-46, 51, 56, 57 and 63-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/15/2010 has been entered.

Applicants amendments to the claims filed 07/15/2010 have been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-34,36-46,51,56-57,63-65 and 68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically the examiner could not find support for the new transitional language in claims 33 and 65 "consisting essentially of", nor have applicant led the examiner to where such support may be found in the specification. Additionally the examiner could not find support for

the new transitional language in claim 68 "comprising" nor have applicants led the examiner to where such support may be found in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-38,40-41,42,43,45 and 63 contains the trademark/trade name Noveon or Carbomer or Eudragit or Dentsply or Tragacanth. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of **35 U.S.C. 112**, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the type of water swellable anionic mucoadhesive, anionic pH sensitive film-forming polymer, wax and water soluble or water-swellaable polymer, accordingly, the identification/description is indefinite.

**Claims 33-34,36-46,51,56-57 and 63-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons set forth in the previous office action filed 10/09/2009. A new rejection of claims 67-68 was necessitated by applicant's amendments to the claims.**

***Response to Arguments***

Applicant's arguments filed 07/15/2010 have been fully considered but they are not persuasive.

Applicants assert that they specifically use Eudragits which are synthetic cationic and anionic polymers; therefore applicants believe they should be able to claim any and all anionic polymers known to mankind. This reasoning cannot be true. First even if applicants have support in the specification for negatively charged copolymers of methacrylic acid and acrylic or methacrylic esters (anionic Eudragits), a reasoning the examiner does not believe is true, the applicants only have support for the very narrow genus of Eudragit type of anionic polymers, not every anionic polymer known in the world. There is no nexus between applicants claimed anionic film forming polymers and the very narrow anionic Eudragit polymer exemplified in the specification.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 33-34,36-37,42-46,56-57,65 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slavtcheff et al (US 6,270,783 B1) in view of Suzuki et al. (US 4,715,369), for the reasons set forth in the previous office actions filed 10/09/2009 and 07/15/2010. A new rejection of claim 67 was necessitated by applicant's amendments to the claims; this claim is rejected for the reasons of record in previous office actions (duplicate of previous claim 33).

Applicant's arguments filed 02/08/2010 have been fully considered but they are not persuasive.

Applicants assert that Slavtcheff fails to teach or hint at a mucoadhesive layer for use on wet mucosal surfaces as claimed. The new limitation on adhering to a mucosal surface is just an intended use of the adhesive and the adhesive taught by the combination of Slavtcheff and Suzuki would be capable of the same use since the combinations of references describe the same adhesive claimed. Furthermore applicants claim skin as a mucosal site in claim 56, thus skin would not seem to be precluded by the claims. The pH sensitive mucoadhesive layer is defined within the claim by what it comprises, a water-insoluble swellable anionic mucoadhesive polymer and at least one anionic pH-sensitive film-forming polymer. As disclosed in the previous office action Slavtcheff discloses an adhesive composition containing anionic film forming polymers and Carbomer structuring agents. Carbomer is claimed as a water-insoluble swellable anionic mucoadhesive polymer, thus Slavtcheff discloses the use of both of applicants claimed ingredients in the adhesive composition.

Applicants further argue that Slavtcheff does not use the phrase "pH sensitive mucoadhesive polymer" when describing the Carbomer in the adhesive layer. This argument cannot be correct, simply because applicants call Carbomer by another name than Slavtcheff (describes it as a "structuring polymer") does not mean that the compound is not the same. The same compound is the same no matter what the name is given to that compound.

Applicants further argue that the examiner has not provided a reasoning for picking the ingredients of Slavtcheff that read on the claimed pH-sensitive anionic mucoadhesive for delivering a molecule of interest to mucosal area. In response to applicant's argument that the references do not describe a pH-sensitive anionic mucoadhesive for delivering a molecule of interest to mucosal area, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Slavtcheff clearly discloses that Carbomer and anionic film forming polymers are useful ingredients in a dry to the touch adhesives.

Applicants further argue that Slavtcheff merely describes numerous ingredients for use in the adhesive and there would be no reason to choose those particular agents and it would be an undue burden to combine the ingredients which read on applicant claimed invention.

This argument is unclear, clearly Slavtcheff describes Carbomers and anionic film forming agents as ingredients in the dry to touch adhesive, while other film-forming agents are possible (cationic or neutral) those additional species do not preclude the disclosure of an anionic film forming polymer.

Claims 33,34,36-46,51,56,57 and 63-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slavtcheff et al (US 6,270,783 B1) in view of Suzuki et al. (US 4,715,369) in view of Mantelle et al. (US 6,562,363 B1), for the reasons set forth in the previous office actions filed 10/09/2009 and 07/15/2010.

Regarding claim 68 it would be obvious to one of ordinary skill that a combination of just two adhesives, anionic Eudragit and Noveon could be used in combination in an adhesive layer from the combined disclosure of the references above. Since both compounds are disclosed as useful adhesive components one of ordinary skill in the art would have a high expectation of success in using the two compounds together and expect an additive type of effect from that combination. It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The reason to combine them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional bioadhesives.

Applicants assert there is no reason for the skilled artisan to consider combining Slavtcheff and Mantelle with a reasonable expectation of success independent of mere recitations of ingredients to arrive at applicants claimed pH-sensitive mucoadhesive layer as claimed.

As applied above applicant's argument that the references do not describe a pH-sensitive anionic mucoadhesive for delivering a molecule of interest to mucosal area is not persuasive, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. Clearly adhesive technology is a mature field and one of ordinary skill in the art would have a high



expectation of success in adding adhesives known in the prior art. There is nothing difficult or undue in using compounds that are described as useful in the same field of endeavor, in this instance adhesives, and substituting or combining those compounds.

Applicants lastly argue that Mantelle expressly leads on of ordinary skill in the art to use PVP. As noted above one of ordinary skill in the art could combine any one of the disclosed adhesive compounds of Mantelle and add them in the adhesive of Slavtcheff. In addition to the rebuttal above even if one of ordinary skill in the art added the PVP taught in Mantelle to an adhesive composition it would not be precluded from independent claims 33,66 and 67. Perhaps applicants think that PVP is excluded by the transitional phrase "consisting essentially of" now used in claims 33 and 66. However, the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. Applicants claim an adhesive, Mantell teaches an adhesive containing PVP, clearly PVP would not materially affect the basic and novel characteristic(s)" of the claimed invention drawn to an adhesive since Mantell uses this ingredient and the composition functions as an adhesive.

Claims 33-34,36-46,56-57 and 63-67 rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle et al. (US 6,562,363 B1) in view of Suzuki et al. (US 4,715,369).

Mantelle discloses bioadhesive compositions for topical administration of an active agent that included polypeptides, antibacterials, anesthetics, analgesics and

others to the skin or mucous membranes. See abstract, col 9 lin 44-col 13 lin 35 and claims. The bioadhesive contained a backing material. See col 3 lin 39-41. Suitable bioadhesives included Noveon polycarbophils and the bioadhesive could further comprise a pressure sensitive adhesive including acrylic adhesives (Eudragit L100 same as S100 exemplified). See col 6 16-24, col 36 lin 66-col 38 lin 6 and example 2, particularly composition 42. Mantelle is silent on the ratio of the bioadhesive polymer carbomer to pressure sensitive adhesive Eudragit, however such adjustments to the concentration of ingredients within an adhesive is no more than ordinary and routine optimizations. One of ordinary skill in the art has good reason to optimize the concentrations of ingredients within an adhesive composition for active agent deliver to the skin or mucosal surface to optimize the stickiness of the adhesive. For instance one would optimize the stickiness so that the patch, bandage etc. provided the desired adhesion to skin or mucosa surface without being so sticky as to cause irritation or injury.

Mantelle does not disclose the thickness of the cosmetic strip or the use of a wax backing layer. These deficiencies however are taught by Suzuki as described in the previous office action filed 01/02/2009. Suzuki discloses the advantages of using a thin layer for adhesive patches and the use of a wax backing layer. Suzuki disclosed that thin films advantageously alleviates the feeling of touchy discomfort and makes itself applicable to flexure. Thus from the disclosure of Mantelle and Suzuki applicants claimed thin bi-layer wax film containing an adhesive containing anionic polymers and a wax backing layer would have been obvious since the two references are related to the

same general field of endeavor, bioadhesives for treating injury. Thus one of ordinary skill in the art would have a high expectation of success in using the backing layer of Suzuki and substituting it for the backing layer of Mantelle. The reason to make such a modification to Mantelle would be that the thin backing layer of Suzuki would provide a thin adhesive strip which would advantageously alleviate the feeling of touchy discomfort and make itself applicable to flexure.

### **Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1618

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. W. R./

Examiner, Art Unit 1618

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618